

85. **FY:99 Form 10-K.** The same day, March 31, 2000, Organogenesis also filed with the SEC its financial results for full year 1999, pursuant to a Form 10-K signed by defendants Laughlin, Erani and Lopolito, among others. In addition to repeating many of the same misrepresentations made in the Company's release, the 1999 Form 10-K also stated that, Organogenesis "*believe[s] that future capital comprised of product sales, research and development support payments and debt equity financings will be sufficient to fund future operations into 2001 . . .*" The Form 10-K also represented that its marketing partner, Novartis, had "*a marketing and sales force[] with technical expertise and distribution capability*" and that "*[w]e expect Apligraf commercial sales to continue to increase.*" The Form 10-K further stated that:

Cost of product sales exceeded product sales due to the start-up costs of new product introduction and the high costs associated with low volume production. *We expect production volume to increase and our margins to improve. We expect to continue to expand production operations during the next 12 months.*

* * *

We expect production costs to exceed product sales for the near term due to start-up expenses and the high costs associated with low volume production. However, *we expect production volume to increase.*

86. Following the filing of Organogenesis' 2000 Form 10-K, shares of the Company traded as high as \$12.60 per share on March 31, 2000.

87. The statements made by defendants and contained in the Company's March 31, 2000 release and 1999 Form 10-K, reproduced herein *supra*, were each materially false and misleading and were known by defendants to be false at that time, or were recklessly disregarded as such for the following reasons:

(a) Defendants failed to disclose the material adverse factors affecting the Company alleged in paragraphs 59-67, *supra*.

(b) Contrary to defendants' representation that Novartis had "*a marketing and sales force[] with technical expertise and distribution capability*," Novartis' marketing team did not have the proper training, experience or expertise in selling a product like Apligraf, with the result that Novartis' efforts to market Apligraf suffered significantly. In fact, as alleged above, according to former employees of Novartis and Organogenesis, Novartis "**had no idea what they were doing**" when it came to marketing a living-tissue product like Apligraf.

(c) Contrary to defendants' suggestion, the Company's planned focus on "driving down per unit manufacturing costs" and implementing "more efficient methods of production" would not achieve profitability for the Company. As defendants were well aware at the time but failed to disclose, and as confirmed by former employees of Organogenesis, Organogenesis was losing money on every unit of Apligraf that it produced because of the terms of the disadvantageous terms of the Novartis marketing agreement — under which Novartis shared revenue from Apligraf sales that was well below the product's manufacturing cost to Organogenesis and reimbursed Organogenesis for production costs in connection with unsold units at only a fraction of the actual costs of production.

(d) Defendants' representation that they expected Apligraf "commercial sales to increase" was untrue given the marketing problems that Novartis was experiencing because of inadequate marketing support and the significant problems with the manufacturing and distribution of Apligraf that were causing frustration among purchasers, leading to reluctance among physicians to order or re-order Apligraf and damaging Apligraf's future sales development prospects.

(e) Contrary to defendants' representations that production volume would increase and that as a consequence of that increase the Company's margins would improve, as

confirmed by former employees of Organogenesis, the Company was experiencing serious problems in manufacturing Apligraf and there was “no way” the Company could feasibly mass-produce Apligraf. Further, it was not true that costs exceeded sales due to start-up costs and the high costs of low volume production, and that the Company’s margins would improve as production volume increased. As confirmed by former employees of Organogenesis, it was well known by the upper management of the Company that, throughout the Class Period, Organogenesis was losing money on every sale of Apligraf because of the disadvantageous terms of the Novartis marketing agreement — under which Novartis shared revenue from Apligraf sales that was well below the product’s manufacturing cost to Organogenesis. Given the terms, and the revised terms, of the Novartis marketing agreement — which caused Organogenesis to lose money on every unit of Apligraf that it produced — *far from lowering costs, the more units of Apligraf that Organogenesis produced, the greater its losses would be.*

(f) Defendants’ representations touting the oversubscription of the Company’s stock offering as a result of investors’ “strong interest in the Company” were materially misleading and incomplete given that defendants failed to disclose the obstacles that existed in accessing essential future funding. Defendants’ representations misleadingly conditioned investors to believe that the Company would be able to raise the additional equity and debt financing necessary to keep the Company operational and achieve profitability. As later revealed, the Company in fact did not have access to such funding.

(g) Contrary to defendants’ representations that they expected to “continue to expand production operations,” according to former employees of the Company, Organogenesis was experiencing serious problems in manufacturing Apligraf and there was “no way” the

Company could feasibly mass-produce Apligraf given the Company's inadequate production infrastructure and processes.

88. **Stein Stock Registration.** Taking further advantage of the artificial inflation in the price of Organogenesis that defendants' false statements had caused, on or about April 21, 2000, defendant Stein caused the Company to file with the SEC a Registration Statement allowing him to register for sale over 732,000 shares of his personally held Organogenesis stock. The Registration Statement, signed by defendants Laughlin, Lopolito and Erani, among others, stated in part the following:

CALCULATION OF REGISTRATION FEE

Title of securities to be registered	Amount to be registered(1)	Proposed maximum offering price per share(2)	Proposed maximum aggregate offering price(2)	Amount of registration fee
Common Stock, \$.01 par value (3)	732,423	\$9.4375	\$6,912,242.10	\$1,824.83

* * *

This Prospectus is part of a Registration Statement we filed with the Securities and Exchange Commission for registration of up to 732,423 shares of Common Stock for sale by the selling stockholder listed on page 12 of this prospectus.

Each of the shares to be sold either were issued upon the exercise of options held by the selling stockholder. The selling stockholder may offer his common stock through transactions on the American Stock Exchange; in private transactions at current market prices; or at negotiated prices.

We will not receive any of the proceeds from the selling stockholder's sale of his common stock.

* * *

USE OF PROCEEDS

We will receive no net proceeds from the sale of the common stock. *All proceeds will be realized by the selling stockholder.*

SELLING STOCKHOLDER

The selling stockholder, Herbert M. Stein, is offering shares which have been acquired by him upon the exercise of options granted under a stock option grant. Mr. Stein previously served as Chairman and Chief Executive Officer of the Company until his retirement on December 31, 1999 and as a member of the Board of Directors of the Company until March 17, 2000. The following table lists the selling stockholder and other information regarding beneficial ownership of the common stock by the selling stockholder as of March 29, 2000:

Name	Number of Shares Beneficially Owned Prior to the Offering	Number of Shares Being Offered	Number of Shares Beneficially Owned After Offering	Percentage of Class to be Beneficially Owned After Offering
Herbert M. Stein	2,086,597	723,423	1,363,174	4.0%

This registration represented almost half of defendant Stein's personal holdings (excluding approximately 1.1 million shares of common stock held by H.M. Stein Associates to which defendant Stein disclaimed beneficial ownership).

89. **1Q:00 Results.** On May 11, 2000, Organogenesis issued a release published on *Business Wire* which purported to announce financial results for the first quarter of 2000. Defendants again stated that the Company's quarterly results were "consistent with the Company's ongoing transition from being a research company to being a research-based operating company," in addition to stating the following:

Revenue from product sales to related party and others were \$646,000 for the first quarter of 2000 compared with \$543,000 for the fourth quarter of 1999. The growth in product revenue was due to increased sales of Apligraf(R) to Novartis. Total revenues were \$1,084,000 for the first quarter of 2000 compared with \$1,015,000 for the fourth quarter of 1999. Total costs and expenses were \$7,770,000 for the first quarter of 2000 compared with \$9,368,000 for the fourth quarter of 1999, which had

included disproportionately higher occupancy and financing costs. Net loss was \$0.21 per share (or \$6,686,000) for the first quarter of 2000 compared with \$0.27 per share (or \$8,353,000) for the fourth quarter of 1999.

The first quarter of 2000 product revenues of \$646,000 compare with \$318,000 for the first quarter of 1999. The total revenues of \$1,084,000 compare with \$679,000 for the same quarter in 1999 and the total costs and expenses of \$7,770,000 compare with \$6,605,000 for the same quarter in 1999. The net loss of \$0.21 per share (or \$6,686,000) compares with a net loss of \$0.19 per share (or \$5,926,000) for the same quarter in 1999.

This release also quoted defendant Laughlin, as follows:

Key to Apligraf sales development are two factors: obtaining approval for diabetic foot ulcers and gaining standardized Apligraf reimbursement... The Advisory Panel's recommendation earlier this week is a key achievement towards the diabetic foot ulcer indication. We are equally committed to gaining standardized reimbursement for Apligraf. [Emphasis added.]

90. **1Q:00 Form 10-Q.** On or about May 15, 2000, defendants filed with the SEC the Company's financial results for the first quarter of 2000, the period ended March 31, 2000, pursuant to a Form 10-Q, signed by defendants Laughlin and Arcari. The Company's first quarter 2000 Form 10-Q contained the same materially false and misleading financial information as had previously been announced on May 11, 2000, in addition to reporting, in part, the following:

Basis of Presentation

The accompanying unaudited consolidated financial statements of Organogenesis Inc. have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X.... *In the opinion of management, the accompanying consolidated financial statements include all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of the financial position, results of operations and changes in cash flows for the periods presented....*

* * *

Costs and Expenses

Cost of product sales: Cost of product sales was \$1,191,000 for the three months ended March 31, 2000, compared to \$603,000 for the same period in 1999, due to increased unit sales of Apligraf to Novartis. Cost of product sales includes the direct costs to manufacture and package Apligraf and an allocation of our production related indirect costs. *Cost of product sales exceeded product sales due to the start-up costs of new product introduction and the high costs associated with low volume production. We expect production volume to increase and our margins to improve. We expect to continue to expand production operations during 2000.* [Emphasis added.]

91. The statements made by defendants and contained in the Company's May 11, 2000 release and first quarter 2000 Form 10-Q, reproduced herein, *supra*, were each materially false and misleading and were known by defendants to be false at that time, or were recklessly disregarded as such for the following reasons:

- (a) Defendants failed to disclose the material adverse factors affecting the Company alleged in paragraphs 59-67, *supra*.
- (b) It was not true that “[k]ey to Apligraf sales development are two factors: obtaining approval for diabetic foot ulcers and gaining standardized Apligraf reimbursement.” Defendants were aware, but did not disclose, that sales of Apligraf and future sales development prospects were hampered by serious manufacturing and marketing problems, including the Company’s inability to mass produce Apligraf, Novartis’ lack of training, experience and expertise in marketing Apligraf and increasing physician resistance to the product.
- (c) Contrary to defendants’ representations that production volume would increase and that as a consequence of that increase the Company’s margins would improve, as confirmed by former employees of Organogenesis, the Company was experiencing serious problems in manufacturing Apligraf and there was “no way” the Company could feasibly mass-produce Apligraf. Further, it was not true that costs exceeded sales due to start-up costs and the high costs of low volume production, and that the Company’s margins would improve as

production volume increased. As confirmed by former employees of Organogenesis, it was well known by the upper management of the Company that, throughout the Class Period, Organogenesis was losing money on every sale of Apligraf because of the disadvantageous terms of the Novartis marketing agreement — under which Novartis shared revenue from Apligraf sales that was well below the product's manufacturing cost to Organogenesis. Given the terms, and the revised terms, of the Novartis marketing agreement — which caused Organogenesis to lose money on every unit of Apligraf that it produced — *far from lowering costs, the more units of Apligraf that Organogenesis produced, the greater its losses would be.*

(d) Contrary to defendants' representations that they expected to "continue to expand production operations," the Company was experiencing serious problems in manufacturing Apligraf and, according to a former employee of Organogenesis, there was "no way" the Company could feasibly mass-produce Apligraf given the Company's inadequate production infrastructure and processes.

(e) Contrary to defendants' representations, the Company's first quarter 2000 Form 10-Q did not reflect the true financial condition of the Company because it failed to disclose the adverse factors affecting the Company's operations and future viability alleged in subparagraphs (a) through (d) above and in paragraphs 59-67, *supra*.

92. On or about June 14, 2000, as President and Chief Executive Officer of Organogenesis, defendant Laughlin showcased a very positive presentation of the Company at the Annual Sachs Healthcare Conference in Laguna Niguel, CA.

93. On June 20, 2000, Organogenesis issued a release which announced that the FDA had given final approval of Apligraf treatment for diabetic foot ulcers in addition to its previous indication of venous leg ulcers. While no changes had been made to Apligraf for this market

application, the FDA indication purportedly allowed Organogenesis to expand its market base to include this second group of foot ulcer sufferers. On this news, Organogenesis stock traded as high as \$12.75 per share in intra-day trading.

94. **Laughlin on CNBC Power Lunch.** On June 25, 2000, defendant Laughlin appeared on the widely disseminated cable financial news show “Power Lunch,” on the CNBC network. When asked by the CNBC interviewer whether Organogenesis had the ability to obtain profitability through sales of the Company’s only product Apligraf, defendant Laughlin responded, by stating that Organogenesis *“can become profitable and will become profitable with Apligraf alone. The two main drivers of that are diabetic foot ulcer approval which happened last week and getting that standardized Medicare reimbursement, which has been slow going. We’re optimistic....”* [Emphasis added.]

95. **Apligraf Sales 7/00.** On August 2, 2000, Organogenesis issued a release which purported to announce Apligraf sales for the month of July 2000. This release stated that the month “held notable achievements significant to future sales development.” Despite this statement, sales of Apligraf had declined substantially from the prior month, reaching only 912 units in July. Defendant Laughlin, however, suggested that the decline in sales was the result of the “summer vacation period” — not that they were the result of any production problems within the Company or any issues with product quality, product acceptance or Novartis’ marketing.

96. **2Q:00 Results.** On August 14, 2000, Organogenesis issued a release published on *Business Wire* which purported to announce financial results for the second quarter 2000. This quarter defendants stated that the Company was “in the process of transitioning from being a research company to becoming an operating company with a strong research base,” in addition to stating the following:

For the second quarter of 2000, total revenues were \$6.4 million compared with \$0.9 million for the same quarter in 1999. The 2000 revenues include a \$5 million milestone payment from Novartis that was received in March and earned in June with the approval of Apligraf for diabetic foot ulcers. Total costs and expenses were \$8.5 million during the second quarters of both 2000 and 1999. The 1999 expenses included a non-cash charge of \$0.9 million for a technology-related acquisition, while the 2000 expenses show modest increases across each expense category. Net loss was \$2.0 million (\$0.06 per share), compared with a net loss of \$7.6 million (\$0.25 per share) for the same quarter in 1999.

The Company reportedly had \$22.3 million in cash, cash equivalents and investments at June 30, 2000.

97. In addition to reporting the following, the August 14, 2000 release was also used by defendant Laughlin to condition investors to believe that Organogenesis had achieved certain milestones such that it was foreseeable that the Company could achieve profitability in the near-term. In this regard, defendant Laughlin was quoted in the August 14, 2000 release, as follows:

When we announced our first quarter results three months ago, we stated our commitment to achieving *two important drivers of Apligraf sales: FDA approval for diabetic foot ulcers and Medicare reimbursement for the product's cost. We now have tangible achievements in both areas.* Apligraf was approved for diabetic foot ulcers in June and its marketing was launched by Novartis in July. Effective this month, Apligraf qualifies for Medicare reimbursement when used in the hospital outpatient setting, such as a hospital-affiliated wound care center. There has also been progress in gaining Medicare reimbursement for Apligraf applied in the doctor's office, with additional activities underway. [Emphasis added.]

Defendant Laughlin also claimed that the Company had "*further strengthened its manufacturing and management team*" with the addition of a new Vice President of Operations in June 2000.

98. **2Q:00 Form 10-Q.** The same day, August 14, 2000, defendants also filed with the SEC the Company's financial results for the second quarter of 2000, the period ended June 30, 2000, pursuant to a Form 10-Q signed by defendants Laughlin and Arcari. The Company's

second quarter 2000 Form 10-Q contained the same materially false and misleading financial information as had been previously announced, in addition to reporting, in part, the following:

Basis of Presentation

The accompanying unaudited consolidated financial statements of Organogenesis Inc. have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X.... *In the opinion of management, the accompanying consolidated financial statements include all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of the financial position, results of operations and changes in cash flows for the periods presented...*

* * *

COSTS AND EXPENSES

Cost of product sales: Cost of product sales was \$1,243,000 and \$2,434,000 for the three and six months ended June 30, 2000, compared to \$1,126,000 and \$1,730,000 for the same periods in 1999, due to increased unit sales of Apligraf to Novartis. Cost of product sales includes the direct costs to manufacture and package Apligraf and an allocation of our production related indirect costs. *Cost of product sales continues to exceed product sales due to the high costs associated with low volume production. We expect production volume to increase and our margins to improve. We expect to continue to expand production operations during 2000.* [Emphasis added.]

99. **Apligraf Sales 3Q:00.** On October 3, 2000, defendants published a release on *Business Wire* which reported record Apligraf sales for September and the third quarter of 2000 —1081 units in September 2000 and a total of 3,232 units during the third quarter of 2000. In addition to reporting the foregoing, this release also quoted defendant Laughlin who stated that, *“[t]hird quarter Apligraf achievements . . . laid an important foundation for future sales development.”* [Emphasis added.]

100. The statements made by defendant Laughlin during the June 25, 2000 CNBC interview and other statements made by defendants and contained in the Company's August 2,

2000 release and Form 10-Q for the second quarter of 2000, reproduced herein, *supra*, were each materially false and misleading and were known by defendants to be false at that time, or were recklessly disregarded as such for the following reasons:

- (a) Defendants failed to disclose the material adverse factors affecting the Company alleged in paragraphs 59-67, *supra*.
- (b) Contrary to defendants' representation, it was not true that the Company could "become profitable and *will become profitable* with Apligraf alone" and that "the two main drivers" of profitability would be the approval of Apligraf for diabetic foot ulcer approval and the receipt of standardized Medicare reimbursement. As defendants were aware, the disadvantageous terms of the Novartis marketing agreement — under which Organogenesis was losing, and would continue to lose, money on every unit of Apligraf that it produced — ensured that the Company could not achieve profitability through the production and sale of Apligraf. Further, as alleged in paragraphs 59-67, *supra*, the Company was suffering from a host of undisclosed financing, manufacturing, marketing and management problems that were obstacles to the Company's achievement of its purported plan for profitability.
- (c) For the same reasons stated in subparagraph (b) above, defendants' statements that "the two important drivers of Apligraf sales" were obtaining approval for diabetic foot ulcers and gaining standardized Apligraf reimbursement misled investors into believing that these were the last two pieces of the sales puzzle, and that given that the Company had now achieved "tangible achievements in both areas," sales were poised to increase, allowing the Company to achieve profitability. Defendants were aware, but did not disclose, that sales of Apligraf and future sales development prospects were hampered by serious manufacturing and marketing problems, including the Company's inability to mass produce Apligraf, Novartis' lack

of training, experience and expertise in marketing Apligraf and increasing physician resistance to the product.

(d) Contrary to defendants' representations that they expected to "continue to expand production operations," the Company was experiencing serious problems in manufacturing Apligraf and there was "no way" the Company could feasibly mass-produce Apligraf given the Company's inadequate production infrastructure and processes.

(e) Defendants' representation that the Company had made "notable achievements significant to future sales development" in July 2001 despite declining sales volume, and their suggestion that the decline was the result of the "summer vacation period" was materially misleading and incomplete given that the Company's sales were adversely affected by the significant manufacturing and marketing problems, including problems with product quality, product acceptance and Novartis' marketing, and that these problems were actually exacerbating, rather than improving, "future sales development."

(f) Contrary to defendants' representation that they had "further strengthened" the Company's "manufacturing and management team," recent turnover among the Company's senior management and directors, including the departure of defendant Stein and others, as well as infighting among senior management, were weakening the Company's management team and adversely affecting the Company's operations.

(g) Contrary to defendants' representations that production volume would increase and that as a consequence of that increase the Company's margins would improve, as confirmed by former employees of Organogenesis, the Company was experiencing serious problems in manufacturing Apligraf and there was "no way" the Company could feasibly mass-produce Apligraf. Further, it was not true that costs exceeded sales due to start-up costs and the

high costs of low volume production, and that the Company's margins would improve as production volume increased. As confirmed by former employees of Organogenesis, it was well known by the upper management of the Company that, throughout the Class Period, Organogenesis was losing money on every sale of Apligraf because of the disadvantageous terms of the Novartis marketing agreement — under which Novartis shared revenue from Apligraf sales that was well below the product's manufacturing cost to Organogenesis. Given the terms, and the revised terms, of the Novartis marketing agreement — which caused Organogenesis to lose money on every unit of Apligraf that it produced — *far from lowering costs, the more units of Apligraf that Organogenesis produced, the greater its losses would be.*

(h) Defendants' representation that they had established an "important foundation for future sales development" was materially misleading and incomplete given that defendants failed to disclose the fundamental manufacturing, marketing and management problems alleged above, which had actually established a weakened foundation for developing future sales.

(i) Contrary to defendants' representations, the Company's second quarter 2000 Form 10-Q did not reflect the true financial condition of the Company because it failed to disclose the adverse factors affecting the Company's operations and future viability alleged in subparagraphs (a) through (h) above and in paragraphs 59-67, *supra*.

101. **3Q:00 Results.** On November 14, 2000, Organogenesis issued a release published on *Business Wire* which purported to announce financial results for the third quarter 2000. Again, defendants heralded the achievements of Apligraf, reporting that Organogenesis was still "in the process of transitioning from being a research Company to becoming an operating Company with a strong research base." This release also stated, in part, the following:

For the three months ended September 30, 2000, total revenues were \$1.4 million compared with \$0.9 million for the same quarter in 1999. The increase was due to increased product sales to related party and others and increased income from grants and interest. Total costs and expenses were \$8.3 million during the third quarter of 2000 compared with \$7.4 million for the same quarter in 1999. The increase was due to increased cost of product sales, research and development expenses, interest expense and general and administrative expenses. Net loss was \$6.9 million (\$0.20 per share), compared with a net loss of \$6.5 million (\$0.21 per share) for the same quarter in 1999.

In addition to the foregoing, defendant Laughlin was also quoted in this release as conditioning investors to believe the following:

This summer we made important progress in several areas central to Apligraf sales development. Apligraf was approved and launched for diabetic foot ulcers, qualified for Medicare reimbursement when used in the hospital outpatient setting and marketer Novartis expanded the field force selling the product. We believe the Apligraf sales growth seen in the third quarter is the beginning of the effect of these achievements on sales development. *While unit volumes are still small, which adversely affects our cost of production, the trend is encouraging.*

102. **3Q:00 Form 10-Q.** The same day, November 14, 2000, defendants also filed with the SEC pursuant to Form 10-Q the Company's financial results for the third quarter of 2000, the period ended September 30, 2000, signed by defendants Laughlin and Arcari. The Company's Form 10-Q for the third quarter of 2000 contained the same materially false and misleading financial information as had previously been announced, in addition to reporting, in part, the following:

Basis of Presentation

The accompanying unaudited consolidated financial statements of Organogenesis Inc. have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X.... *In the opinion of management, the accompanying consolidated financial statements include all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of the financial position,*

results of operations and changes in cash flows for the periods presented....

* * *

COSTS AND EXPENSES

Cost of product sales: Cost of product sales was \$1,310,000 and \$3,744,000 for the three and nine months ended September 30, 2000, compared to \$969,000 and \$2,699,000 for the same periods in 1999, due to increased unit sales of Apligraf to Novartis. Cost of product sales includes the direct costs to manufacture and package Apligraf and an allocation of our production related indirect costs. *Cost of product sales continues to exceed product sales due to the high costs associated with low volume production. We expect production volume to increase and our margins to improve.* [Emphasis added.]

103. **Apligraf Sales 11/00.** Later, on December 4, 2000, Organogenesis announced that November sales of Apligraf were 1488 units — a new record monthly high. In addition, this release again quoted defendant Laughlin who stated that, “[w]e are clearly beginning to see acceleration in the growth of Apligraf sales. October and November establish a new, *higher sales base on which to build*. While it is difficult to predict how the December holidays will impact sales, *we expect to begin seeing in the first quarter the impact of the additional sales representatives that started this past summer.*” [Emphasis added.]

104. The statements made by defendants and contained in the Company’s October 3, 2000 and November 14, 2000 releases and in the Form 10-Q for the third quarter of 2000, reproduced herein, *supra*, were each materially false and misleading and were known by defendants to be false at that time, or were recklessly disregarded as such for the following reasons:

(a) Defendants failed to disclose the material adverse factors affecting the Company alleged in paragraphs 59-67, *supra*.

(b) Contrary to defendants' representations that the "trend" with respect to its ability to increase unit volumes and thus favorably affect the cost of production was "encouraging," as confirmed by former employees of the Company, Organogenesis was experiencing substantial manufacturing problems, which were retarding and hindering the expansion of production scale. Further, defendants were aware but failed to disclose that the most important factor affecting cost of production was not "unit volumes," but rather the unfavorable terms of the Novartis marketing agreement, under which Organogenesis was reimbursed for only a fraction of production costs in connection with units *not* sold, and received a share of revenue on units that *were* sold that was far below cost.

(c) Contrary to defendants' representations that production volume would increase and that as a consequence of that increase the Company's margins would improve, as confirmed by former employees of Organogenesis, the Company was experiencing serious problems in manufacturing Apligraf and there was "no way" the Company could feasibly mass-produce Apligraf. Further, it was not true that costs exceeded sales due to start-up costs and the high costs of low volume production, and that the Company's margins would improve as production volume increased. As confirmed by former employees of Organogenesis, it was well known by the upper management of the Company that, throughout the Class Period, Organogenesis was losing money on every sale of Apligraf because of the disadvantageous terms of the Novartis marketing agreement — under which Novartis shared revenue from Apligraf sales that were well below the product's manufacturing cost. Given the terms, and the revised terms, of the Novartis marketing agreement — which caused Organogenesis to lose money on every unit of Apligraf that it produced — *far from lowering costs, the more units of Apligraf that Organogenesis produced, the greater its losses would be.*

(d) Defendants' public statements touting the "record number" of sales in November 1999, the fact that recent sales established a "higher sales base on which to build" and that the Company expected to see "the impact of the additional sales representatives" in the first quarter of 2001 was materially misleading and incomplete given that, as confirmed by several former employees of Organogenesis, the Company was experiencing serious manufacturing and marketing problems that were inhibiting sales and damaging future sales development prospects. Further, as defendants knew, Novartis' marketing team did not have the proper training, experience or expertise in selling a product like Apligraf, with the result that Novartis' efforts to market Apligraf were suffering significantly.

(e) Contrary to defendants' representations, the Company's Form 10-Q for the third quarter of 2000 did not reflect the true financial condition of the Company because it failed to disclose the adverse factors affecting the Company's operations and future viability alleged in subparagraphs (a) through (d) above and in paragraphs 59-67, *supra*.

105. 500,000 Share Repurchase. On December 6, 2000, defendants issued a release which announced that the Board of the Company had authorized the repurchase of up to 500,000 shares of Organogenesis common stock — "at the discretion of management." According to defendant Laughlin, the decision to purchase the Company's stock was made by the Board because, "[o]ur Board is sensitive to shareholder dilution and *views current market conditions as an opportunity to purchase shares that the Company considers to be undervalued in view of our prospects.*" [Emphasis added.] In addition, defendant Laughlin also stated that, "the decision to authorize a stock buyback program demonstrates the confidence our Board has in the Company's future." At the time of this announcement, shares of the Company were trading at approximately \$7.50 per share.

106. **Apligraf Sales January 2001.** On February 5, 2001, Organogenesis announced that Apligraf sales had reached another record in January 2001, with 1771 units sold during that period. In addition, this release again quoted defendant Arcari who stated that, “[w]e are pleased with the acceleration being seen in Apligraf sales growth.”

107. **Laughlin on CNBC Power Lunch February 27, 2001.** On February 26, 2001, Organogenesis issued a release which announced the broadening of its 1996 marketing agreement with Novartis Pharma AG — an agreement which purportedly gave Organogenesis the right for three years to sell Novartis up to \$20 million in equity. Under the purported terms of this deal, Organogenesis would also receive funding from Novartis to upgrade the Company’s manufacturing plants and equipment. The following day, February 27, 2001, defendant Laughlin again appeared on nationally televised cable news show CNBC Power Lunch, during which he was interviewed by Bill Griffeth, and stated, the following:

GRIFFETH: What kind of an increase in revenue do you expect from this expansion of the deal with Novartis?

LAUGHLIN: Let me just run through the deal. And you are right, *it is a turning point for us. It is a major improvement in our economic situation.* Unfortunately, I can’t give you the precise details of the deal but let me ---

LAUGHLIN: [L]et me tell you the major elements of what it is. We have granted Novartis the rights to two additional living tissue products, one that will be entering clinical trials in the next 30 to 60 days and one that is in research. In exchange for that, *we will receive a substantial increase in the percentage of the revenue* for our living tissue product, which is actually on the market today, called Apligraf. *We will also receive funding for a number of different areas which will enable us to expand our business, get into additional markets and drive down our costs.* We also received a \$20 million stock put. *So any time during the next three years we are able at our discretion and our option to sell Novartis \$20 million of shares.* We may or may not do that, but *it is wonderful safety net to have in our pocket.*

GRIFFETH: Right. Now, as far as the product agreement goes, though, I know you are meeting with Wall Street analysts to talk about this. Are you raising guidance, though, as far as revenue for this year as a result of this?

LAUGHLIN: What we are doing and the thing people have been most interested in is giving them guidance on our profitability. *What we now feel with the increased revenue, with the funding support that we will get, we are now targeting to pass through break even and reach profitability in the second quarter of next year — sorry, the third quarter of next year.*

GRIFFETH: Third quarter of next year. OK. And as a result of this, I am curious, I mean are you finding or at least receiving approval for new applications for Apligraf? I am wondering why Novartis is doing this now. I know I should ask them but maybe you can provide some guidance on that.

LAUGHLIN: I think *they are truly convinced that there is major business here.Everything is coming together. I think they are saying, yes, this is working. This is going to be a very big business. Let's get into it deeper. Let's commit to the business.*

* * *

GRIFFETH: Now and you factor, when you provide this guidance for break even, is that a part of that guidance of the anticipated approval of those products and when they might be available for market?

LAUGHLIN: *As we look into the things that go into our break even we are targeting to reach break even with or without those approvals.* One thing that we will hit before break even is we hope to be approved for launch into the European market in approximately the second quarter of next year. [Emphasis added.]

At the time of this interview shares of Organogenesis traded at above \$12.00.

108. The statements made by defendant Laughlin during the February 27, 2001 CNBC interview and those statements made by defendants and contained in the Company's February 5, 2001 release, reproduced herein, *supra*, were each materially false and misleading and were known by defendants to be false at that time, or were recklessly disregarded as such for the following reasons:

- (a) Defendants failed to disclose the material adverse factors affecting the Company alleged in paragraphs 59-67, *supra*.
- (b) Contrary to defendants' representations that the Company's stock was "undervalued in view of our prospects," defendants knew but failed to disclose that defendant Erani had sought to have stock brokers "*manipulate the market for the Company's stock.*"

Further, defendants knew but failed to disclose that the Company's ultimate prospects for achieving profitability were severely compromised by the problems alleged in paragraphs 59-67 above, including the Company's serious manufacturing and marketing problems, its inability to access as necessary adequate funding to keep the Company viable, the difficulties in achieving reimbursement for Apligraf, and the disruptive effect on operations that high turnover and infighting among the Company's senior management was having, and would continue to have for the foreseeable future.

(c) Defendant Laughlin's representation that Novartis' agreement to grant Organogenesis a \$20 million put option was evidence of Novartis' conviction that "everything is coming together" and that "yes, this is working" and "is going to be a very big business" was materially misleading and incomplete for the same reasons as alleged in subparagraph (b) above.

(d) Contrary to defendant Laughlin's representation that under the \$20 million put option with Novartis the Company was "able *at our discretion and our option* to sell Novartis \$20 million of shares" and that the put option was a "wonderful safety net to have in our pocket" was untrue. As later revealed by defendants, the Company did not have the ability to raise the full amount of that funding option at the discretion of the Company. As defendants knew but failed to disclose at the time, significant conditions precedent to the exercise of the put option prevented the Company from accessing \$10 million of the put option funding, which ultimately led to the Company's inability to fund operations in 2002. Thus, the "safety net" that defendants represented they had secured for the Company was only an illusion.

(e) Defendant Laughlin's statements that the revised Novartis marketing agreement was a "turning point" for the Company and a "major improvement in our economic situation" and that the Company would receive "a substantial increase in the percentage of the

revenue" were untrue and materially misleading. As confirmed by former employees of the Company, even under the revised terms of the marketing agreement, Organogenesis' share of revenue from Apligraf sales remained well below Organogenesis' manufacturing costs and could not lead to profitability. Further, even under the revised terms of the marketing agreement, Organogenesis was still required to manufacture Apligraf in conformity with Novartis sales forecasts, which, according to a former employee of Organogenesis, were "always inflated."

(f) Contrary to defendant Laughlin's representation that "the increased revenue" and "the funding support that we will get" put the Company in the position to "pass through break even and reach profitability" by the third quarter of 2002, defendants knew that there was no way the Company could ever achieve profitability — much less achieve it by the third quarter of 2002 — based on the increased revenue from the revised Novartis marketing agreement and the \$20 million put option with Novartis. Defendants were aware under the revised agreement Organogenesis would continue to lose money on every unit of Apligraf produced. Further, as defendants knew but did not disclose at the time, the Company did not have the ability to raise the full amount of the \$20 million put option.

(g) Contrary to defendant Laughlin's representation that the Company expected to "break even with or without" approvals of additional products, defendants knew that given the Company's loss of money on every unit of Apligraf under the revised Novartis marketing agreement and the restrictions on the exercise of the \$20 million put option there was no way that the Company could break even based on sales of Apligraf alone.

109. **Needham Report.** Following defendant Laughlin's well received CNBC appearance, analysts at Needham & Co. issued a report on Organogenesis, initiating a "Buy"

rating and a near term price target of \$16-\$18 per share on Organogenesis stock, and stating in part the following:

INVESTMENT OPINION

We are initiating coverage of Organogenesis Inc. with a ***Buy rating and a 12-month target price range of \$16-\$18.*** Management of skin disorders requiring tissue replacement represents a major unmet need. A leader in its segment of the \$400 billion healthcare arena of regenerative medicine, ORG has developed Apligraf, currently approved for two of the most common chronic wounds (venous stasis ulcers and diabetic foot ulcers).

* * *

We believe ORG is currently undervalued compared to its peers. Applying two methods of valuation (market capitalization to revenue ratio of 11x as well as P/E ratio of 35x) to our 2004 estimates and discounting back at 10% annually, ***we arrive at a 12-month target range of \$16-\$18.*** [Emphasis added.]

110. **Apligraf Sales 2/01.** On March 5, 2001, Organogenesis announced that sales of Apligraf had reached another monthly record, with 1729 units sold in February 2001. In addition, this release again quoted defendant Arcari who stated that, ***“Apligraf sales are showing sustained growth acceleration.*** Average daily sales in February surpassed those in January, and both are ahead of the level seen in our record fourth quarter. ***We are particularly pleased with this acceleration, because under the recently amended agreement with Novartis, Organogenesis now receives significantly higher payments for Apligraf.”*** [Emphasis added.]

111. **Erani’s Refusal To Provide Standard Audit Confirmations to PricewaterhouseCoopers.** Unbeknownst to the public, as stated by defendant Arcari — then the Company’s CFO — in the Confidential Arcari Document obtained by plaintiffs’ counsel, in March 2001 defendant Erani, then Chairman of the Board of Organogenesis, “[r]efused to sign standard audit confirmations sent to him by PricewaterhouseCoopers, the Company’s auditors, relating to his holdings of the Company’s convertible debt.” According to the Confidential Arcari Document, “this eroded PricewaterhouseCoopers [sic] confidence in managements [sic]

and the Boards [sic] representations.” The Confidential Arcari document further states that other actions by Erani led to a “loss of the Company’s credibility with the Company’s service providers including . . . independent accountants.”

112. 4Q and FY:00 Results. On March 30, 2001, Organogenesis issued a release published on *Business Wire* which purported to announce financial results for the fourth quarter and full year 2000, as follows:

For the three months ended December 31, 2000, total revenues were \$1.5 million compared with \$0.9 million for the same quarter in 1999.... Total operating costs and expenses were \$8.5 million during the fourth quarter of 2000 compared with \$8.9 million for the same quarter in 1999.... Net loss was \$7.4 million (\$0.21 per share) for the fourth quarter of 2000 compared with a net loss of \$8.4 million (\$0.27 per share) for the same quarter in 1999.

For the year ended December 31, 2000, total revenues were \$10.2 million compared with \$2.7 million in 1999.... The 2000 full-year revenues include a \$5 million milestone payment from Novartis for our achievement of FDA approval of Apligraf for diabetic foot ulcers. Full-year revenues also include \$1.1 million in research and development support from Novartis recognized in 2000 under SAB 101. Total operating costs and expenses were \$31.6 million in 2000 compared with \$30.6 million in 1999.... Net loss was \$22.3 million (\$0.66 per share) in 2000 compared with a net loss of \$28.4 million (\$0.93 per share) in 1999. When the one-time cumulative effect charge against income due to adoption of SAB 101 is included, the 2000 net loss becomes \$28.6 million (\$0.85 per share).

In addition to the foregoing, defendant Laughlin also stated that defendants were also keeping a tight control over expenses and costs and that Apligraf sales were driving revenues, as follows:

Our increased product revenue in the fourth quarter reflects a significant increase in our unit sales growth rate, compared to the prior quarter. Our first quarter 2001 financials will show an *important increase in revenue due to a continuation of this higher unit growth rate* as well as the *significantly higher revenue per unit* which we now receive from Novartis. *We are keeping a tight control on our corporate expenses while implementing programs to reduce our manufacturing costs.* [Emphasis added.]

113. 2000 Form 10-K. The same day, March 30, 2001, Organogenesis also filed with the SEC its financial results for full year 2000, pursuant to Form 10-K, signed by defendants

Laughlin, Erani and Arcari, among others. In addition to repeating many of the same misrepresentations made in the Company's release, the 2000 Form 10-K also stated that Apligraf was "*mass-produced*" and "*available to physicians on demand*." In the section of the Form 10-K entitled, "Management's Discussion and Analysis of Financial Condition and Results of Operations" ("MD&A") defendants also touted the purported benefits of the recent amendment to the Novartis marketing agreement, stating that the amendment "*significantly increases payments we receive for Apligraf units*." The MD&A section of the Form 10-K further stated that although Organogenesis had "limited experience in sales, marketing and distribution" the Company had "developed a *long-term strategic relationship with Novartis, who has marketing and sales forces with technical expertise and distribution capability*." The MD&A section of the Form 10-K also stated that "*[w]e expect Apligraf commercial sales to continue to increase*" and that "*[w]e expect production volume to increase due to recent Medicare progress with coverage for Apligraf*, FDA approval of Apligraf for use in diabetic foot ulcers and *expanded Novartis sales and marketing support*." The MD&A section of Form 10-K also touted the Company's purported ability to access funding from Novartis and other sources of capital, stating that:

Based upon our current plans, *we believe existing working capital at December 31, 2000, together with the proceeds of product and other revenues in 2001 and proceeds available from exercising a portion or all of a \$20,000,000 equity security put with Novartis, which is at our discretion, will be sufficient to finance operations through at least the first quarter of 2002*. We expect to raise additional funds in 2001 through equity financing. [Emphasis added.]

114. Despite the erosion of PricewaterhouseCoopers' confidence in the representations of the senior officers and directors of Organogenesis and the "loss of the Company's credibility" with the Company's "independent accountants," as alleged above,

PricewaterhouseCoopers on March 31, 2001 issued to the Company's shareholders a "Report of Independent Accountants" certifying Organogenesis' financial statements.

PricewaterhouseCoopers' report, which was included in Organogenesis' 2000 Form 10-K, stated:

In our opinion, the accompanying consolidated financial statements listed in the accompanying index present fairly, in all material respects, the financial position of Organogenesis, Inc. and its subsidiaries at December 31, 2000 and 1999, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2000 in conformity with accounting principles generally accepted in the United States of America. . . . We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America, which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from material misstatement.

115. During April 2001, Organogenesis also hosted presentations at additional analyst conferences, including, but not limited to, the Tucker Anthony Sutro Capital Markets 2001 Health Care Conference, held at the Ritz Carlton in Laguna Niguel, CA, and the Fifth Annual American Stock Exchange Emerging Growth Conference, held at the Grand Hyatt Hotel in New York City. On or about April 17, 2001 analysts at Needham & Co. reiterated their prior "BUY" rating and continued to encourage investors to expect a near-term price target of \$16-\$18 per share.

116. The statements made by defendants and contained in the Company's March 5, 2001 and March 30, 2001 releases and those statements contained in Organogenesis 2000 Form 10-K, reproduced herein, *supra*, including the MD&A section of that Form 10-K were each materially false and misleading and were known by defendants to be false at that time, or were recklessly disregarded as such for the following reasons:

(a) Defendants failed to disclose the material adverse factors affecting the Company alleged in paragraphs 59-67, *supra*.

(b) Contrary to defendants' representation that the \$20 million put option with Novartis was available "at [Organogenesis'] discretion," the Company did not have the ability to raise the full amount of that funding option at the discretion of the Company. As defendants knew but failed to disclose at the time, significant conditions precedent to the exercise of the put option prevented the Company from accessing \$10 million of the put option funding, which ultimately led to the Company's inability to fund operations in 2002.

(c) Contrary to defendants' representation that Apligraf could be, and was being "mass-produced," according to a former Senior Manager of Quality Systems Compliance for Organogenesis during the Class Period, there was "no way" that the Company could commercially mass-produce Apligraf given the Company's inadequate production infrastructure and processes.

(d) Contrary to defendants' representation that the Company made Apligraf "available to physicians on demand," according to a former Tissue Engineering Specialist with Novartis during the Class Period, contamination of the product frequently resulted in physicians not receiving the product when necessary, resulting in increased frustration and disappointment with the product among physicians.

(e) Defendants' representation that "under the recently amended agreement with Novartis, Organogenesis now receives significantly higher payments for Apligraf" was materially misleading and incomplete given that even under the amended agreement Organogenesis would still receive revenue payments that were well below the product's manufacturing cost and that Organogenesis would continue losing money on every unit of Apligraf.

(f) Defendants' representations touting the "important increase in revenue," the "significantly higher revenue per unit" and the "significant[] increases" in "payments the Company receive[d] for Apligraf units" were materially misleading and incomplete for the same reasons stated in subparagraph (e) above.

(g) Defendants' representation that they expected Apligraf "commercial sales to increase" was untrue given the marketing problems that Novartis was experiencing and would continue to experience because of inadequate marketing support and the problems with the manufacturing and distribution of Apligraf that were causing frustration among purchasers, leading to reluctance among physicians to order or re-order Apligraf and damaging Apligraf's future sales development prospects.

(h) Defendants' representations touting "record" sales for the month of February 2001 and "sustained growth acceleration" were materially misleading and incomplete given that, as confirmed by several former employees of Organogenesis, the Company was experiencing serious manufacturing and marketing problems that were inhibiting sales and damaging future sales development prospects. Further, as defendants knew, Novartis' marketing team did not have the proper training or experience in selling a product like Apligraf, with the result that Novartis' efforts to market Apligraf were suffering significantly.

(i) Contrary to defendants' representation that they were "implementing programs to reduce [the Company's] manufacturing costs," the Company was incurring significant manufacturing costs due to the fact that under the revised Novartis marketing agreement, Organogenesis was required to produce Apligraf in sufficient quantities to meet Novartis' "always inflated" sales forecasts. According to former employees of Organogenesis, for every unit of Apligraf manufactured pursuant to Novartis' sales forecasts but not sold,

Organogenesis was required to bear an even greater share of the manufacturing costs than for units that were sold.

(j) Contrary to defendants' representation that Novartis had "marketing and sales forces with technical expertise and distribution capability," Novartis' marketing team did not have the proper training, experience or expertise in selling a product like Apligraf, with the result that Novartis' efforts to market Apligraf were suffering significantly. In fact, as alleged above, according to former employees of Novartis and Organogenesis, Novartis **"had no idea what they were doing"** when it came to marketing a living-tissue product like Apligraf.

(k) Contrary to defendants' representation that they "expect[ed] production volume to increase due to recent Medicare progress with coverage for Apligraf," defendants were encountering significant physician resistance to the product due to difficulties in obtaining Medicare and Medicaid reimbursement for Apligraf.

(l) Defendants' representation heralding "expanded Novartis sales and marketing support" was materially misleading and incomplete given that defendants failed to disclose that Novartis' marketing team did not have the proper training, experience or expertise in selling a product like Apligraf, with the result that Novartis' efforts to market Apligraf were suffering significantly. In fact, as alleged above, according to former employees of Novartis and Organogenesis, Novartis **"had no idea what they were doing"** when it came to marketing a living-tissue product like Apligraf.

(m) Defendants' representation that it had, or had access to, sufficient funds to finance operations through "at least the first quarter of 2002" based in part on "proceeds of product," and proceeds available from the \$20 million put option was untrue. As defendants were well aware but did not disclose (i) revenues from sales of Apligraf were well below costs of

production and thus the product was actually causing the Company to lose money; and (ii) significant conditions precedent to the exercise of the put option prevented the Company from accessing \$10 million of the put option funding, which ultimately led to the Company's inability to fund operations in 2002. Indeed, well before the end of the first quarter of 2002, the Company revealed that it "**would have to curtail or discontinue**" all operations if it could not raise additional funding.

(n) Defendant PricewaterhouseCoopers' certification of the Company's financial statements was materially misleading and incomplete because it failed to disclose that, according to the Confidential Arcari Document, PricewaterhouseCoopers' confidence in the representations of the senior officers and directors of Organogenesis had been eroded and that the Company had lost credibility in the eyes of PricewaterhouseCoopers.

117. **1Q:01 Results.** On April 27, 2001, defendants announced more purported good news. That day, the Company published a release, announcing results for first quarter of 2001, with product revenues "nearly triple over prior year period." This release also stated that the Company had made another amendment to its marketing agreement with Novartis which purportedly gave Organogenesis "significantly higher payments" on sales of Apligraf as well as additional funding support. In addition, this release also stated that:

For the three months ended March 31, 2001, total revenues were \$2.5 million compared with \$1.2 million for the same quarter in 2000. Product sales to related party were \$1.8 million in the first quarter of 2001, compared with \$0.6 million for the same period in 2000, *due to increased sales of Apligraf and the higher payments Organogenesis now receives from Novartis for each unit of Apligraf.*

Total operating costs and expenses were \$8.6 million during the first quarter of 2001 compared with \$7.3 million for the same quarter in 2000. The first quarter of 2001 cost of product sales increased by \$0.7 million due to increased sales of Apligraf. During the same period, research and development costs increased by \$0.6 million due to increased clinical, process development and product development expenses. General and

administrative expenses decreased slightly. Net loss was \$6.5 million (\$0.19 per share) for the first quarter of 2001 compared with a net loss of \$6.4 million (\$0.21 per share) for the same quarter in 2000. When the one-time cumulative effect in change in accounting principle charge due to the adoption of SEC Staff Accounting Bulletin No. 101 - "Revenue Recognition in Financial Statements" is included, the first quarter of 2000 net loss becomes \$12.8 million (\$0.41 per share).

This release also quoted defendant Arcari, as follows:

Our product margin improved significantly over last year. Not only did product revenue increase, but per unit costs decreased as a result of process improvements. We tightly controlled our corporate expenses while increasing our investment in process development to further reduce manufacturing costs. Under our amended agreement with Novartis, we received nearly \$1.0 million in the first quarter of 2001 for manufacturing facility improvements. [Emphasis added.]

118. **1Q:01 Form 10-Q.** On or about April 27, 2001, defendants also filed with the SEC the Company's financial results for the first quarter of 2001, the period ended March 31, 2001, pursuant to a Form 10-Q signed by defendants Laughlin and Arcari. The Company's Form 10-Q for the first quarter of 2001 contained the same materially false and misleading financial information as had been announced previously, in addition to reporting, in part, the following:

Basis of Presentation

The accompanying unaudited consolidated financial statements of Organogenesis Inc. have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X... *In the opinion of management, the accompanying consolidated financial statements include all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of the financial position, results of operations and changes in cash flows for the periods presented....*

* * *

Costs and Expenses

Cost of product sales: Cost of product sales increased 50% to \$2,196,000 in the first quarter of fiscal 2001, from \$1,467,000 for the comparable quarter last year, due to increased unit sales of Apligraf to Novartis. *Cost of product sales includes the direct costs to manufacture and package Apligraf and an allocation of our production related indirect costs. Cost of product sales continues to exceed product sales due to the high costs associated with low volume production. We expect production volume to increase and our margins to continue to improve during 2001.* [Emphasis added.]

* * *

[W]e believe existing working capital at December 31, 2000, together with the proceeds of product and other revenues in 2001 and proceeds available from sales of shares to the underwriter and/or *exercising a portion or all of a \$20,000,000 equity security put with Novartis, which is at our discretion, will be sufficient to finance operations through at least the first quarter of 2002.* We expect to raise additional funds in 2001 through equity financing. [Emphasis added.]

119. The statements made by defendants and contained in the Company's April 27, 2001 release and in the Form 10-Q for the first quarter of 2001, reproduced herein, *supra*, were each materially false and misleading and were known by defendants to be false at that time, or were recklessly disregarded as such for the following reasons:

- (a) Defendants failed to disclose the material adverse factors affecting the Company alleged in paragraphs 59-67, *supra*.
- (b) Defendants' representation that it had, or had access to, sufficient funds to finance operations through "at least the first quarter of 2002" based in part on "proceeds of product," and proceeds available from the \$20 million put option was untrue. As defendants were well aware but did not disclose (i) revenues from sales of Apligraf were well below costs of production and thus the product was actually causing the Company to lose money; and (ii) significant conditions precedent to the exercise of the put option prevented the Company from accessing \$10 million of the put option funding, which ultimately led to the Company's inability to fund operations in 2002.

(c) Contrary to defendants' representation that the \$20 million put option with Novartis was available "at [Organogenesis'] discretion," the Company did not have the ability to raise the full amount of that funding option at the discretion of the Company. As defendants knew but failed to disclose at the time, significant conditions precedent to the exercise of the put option prevented the Company from accessing \$10 million of the put option funding, which ultimately led to the Company's inability to fund operations in 2002.

(d) Defendants' representations touting the "important increase in revenue," the "significantly higher revenue per unit" and the "significant[] increases" in "payments the Company receive[d] for Apligraf units" were materially misleading and incomplete because defendants failed to disclose that even under the amended agreement Organogenesis would still receive revenue payments that were well below the product's manufacturing cost and that Organogenesis would continue losing money on every unit of Apligraf.

(e) Defendants' representations touting a "product revenue increase," the decrease of per unit costs and its investment "to further reduce manufacturing costs" were materially misleading and incomplete given that defendants knew but failed to disclose that the Company was incurring significant manufacturing costs due to the fact that under the revised Novartis marketing agreement, Organogenesis was required to produce Apligraf in sufficient quantities to meet Novartis' "always inflated" sales forecasts. According to former employees of Organogenesis, for every unit of Apligraf manufactured pursuant to Novartis' sales forecasts but not sold, Organogenesis was required to bear an even greater share of the manufacturing costs than for units that were sold.

(f) Contrary to defendants' representations that production volume would increase and that as a consequence of that increase the Company's margins would improve, as

confirmed by former employees of Organogenesis, the Company was experiencing serious problems in manufacturing Apligraf and there was “no way” the Company could feasibly mass-produce Apligraf. Further, it was not true that costs exceeded sales due to start-up costs and the high costs of low volume production, and that the Company’s margins would improve as production volume increased. As confirmed by former employees of Organogenesis, it was well known by the upper management of the Company that, throughout the Class Period, Organogenesis was losing money on every sale of Apligraf because of the disadvantageous terms of the Novartis marketing agreement — under which Novartis shared revenue from Apligraf sales that was well below the product’s manufacturing cost to Organogenesis. Given the revised terms of the Novartis marketing agreement — which caused Organogenesis to lose money on every unit of Apligraf that it produced — *far from lowering costs, the more units of Apligraf that Organogenesis produced, the greater its losses would be.*

(g) Contrary to defendants’ representations, the Company’s Form 10-Q for the first quarter of 2001 did not reflect the true financial condition of the Company because it failed to disclose the adverse factors affecting the Company’s operations and future viability alleged in subparagraphs (a) through (f) above and in paragraphs 59-67, *supra*.

120. **1.9 Million Share Offering.** Later the same day, April 27, 2001, Organogenesis also announced that it had filed a post-effective amendment to its registration statement covering the offering of an additional 1.9 million shares of common stock. Days later on May 8, 2001, Organogenesis published a release on *Business Wire* which announced that the Company had entered into an underwriting agreement with UBS Warburg LLC, as underwriter, providing that on any trading day during the next two years the Company could elect to issue and sell to the underwriter a number of shares of common stock that is not less than 5% and not more than 25%

of the average trading volume of the common stock on the American Stock Exchange for the previous five days, up to an aggregate of 1,900,000 shares.⁴

121. Following the announcement and report of results for the first quarter of 2001, analysts at Needham & Co. again reiterated a “Buy” rating on shares of Organogenesis and continued to advise investors to expect a near-term trading price of \$16-\$18 per share for the Company.

122. **Laughlin Quits.** On May 16, 2001, the Company issued a release announcing that defendant Laughlin had suddenly resigned from Organogenesis and that Michael Sabolinski, former Senior Vice President Medical and Regulatory Affairs, would become President, Chief Executive Officer and a member of the Board of the Company. According to the Company’s release, defendant Sabolinski was primarily responsible for the development of Apligraf. In addition, the release also noted that, “this transition occurs at an important time for Organogenesis as the Company focuses on increasing market penetration with Apligraf and leveraging core technologies to commercialize new products.” While no reason was given for defendant Laughlin’s departure, defendant Sabolinski was quoted in this release as thanking defendant Laughlin for “all he achieved for Organogenesis.”

123. **\$13.5 Million Equity Offering.** On or about May 17, 2001, defendants again capitalized on the artificial inflation in the price of Organogenesis shares that their false and misleading representations had caused, and filed a Prospectus with the SEC in connection with the sale of 1.9 million shares of Organogenesis common stock priced at \$7.75 per share. Gross proceeds from the sales of these shares was estimated, at that time, at over \$13.5 million.

⁴ The sale price of the shares to the underwriter was to be the volume-weighted average price per share at which shares of the common stock traded on the American Stock Exchange during regular trading hours on each purchase date less underwriter’s commissions.

According to the Prospectus, this offering was part of the Company's previously filed, 3.0 million share Shelf Registration Statement.

124. PricewaterhouseCoopers' Refusal to Support Additional Funding Initiatives.

Unbeknownst to the public, as reported by defendant Arcari — then the Company's CFO — in the Confidential Arcari Document obtained by plaintiffs' counsel, in May 2001 defendant Erani, then Chairman of the Board of Organogenesis, “[h]indered the process for gaining approval to exercise the Novartis put option by May 31, 2001, a commitment which was made to PricewaterhouseCoopers (PWC), our independent auditors.” The Company had made this commitment to exercise the put option to PricewaterhouseCoopers in order to “gain [sic] necessary comfort letter from PWC to allow us to sell common shares” under an equity offering with UBS Warburg. The Confidential Arcari Document goes on to state that “[s]ince then PWC has refused to grant any consents or comfort letters because we violated our commitment.” PricewaterhouseCoopers apparently was sufficiently alarmed by the Company's hindrance of this process, and the violation of the Company's aforementioned commitment, that, according to the Confidential Arcari Document, it refused to issue any further “comfort letters” to the Company. PricewaterhouseCoopers, however, never publicly disclosed the Company's “hindering” of the process for obtaining this critical funding or its own refusal to support the Company's future financing initiatives.

125. Apligraf Sales 5/01. On June 5, 2001, Organogenesis announced that sales of Apligraf had again reached above 1750 units, for May 2001. According to defendant Sabolinski, who was quoted in the Company's release, “[t]he May sales figures show sustained support for Apligraf use, and we have accelerated our plans to ramp up production to meet the strong growth forecast for the second half of this year.” [Emphasis added.]

126. While sales for May 2001 were actually less than April sales (1758 units vs. 1813 units), defendants did not revise guidance in any way, and continued to advise analysts and investors that the Company was still on track to register sequential growth in unit sales and achieve profitability. As evidence of defendants' further representations, on June 6, 2001, analysts at Needham & Co. reiterated a "Buy" rating on shares of the Company, and continued to maintain a near-term price target of \$16-\$18 per share.

127. **\$1.44 Million Private Placement.** On June 18, 2001, Organogenesis raised another \$1.44 million through the sale of shares of stock through the UBS Warburg underwriting previously announced. Pursuant to this agreement, between May 21, 2001 and June 18, 2001, defendants caused the Company to sell over 186,000 shares of stock for at least \$1.44 million.

128. **Apligraf Sales 7/01.** On August 2, 2001, Organogenesis announced that sales of Apligraf reached another monthly record sales level: 2015 units sold in July 2001. This release also quoted defendant Sabolinski, as stating that, "*[w]e are delighted with the growth in sales seen between June and July. Apligraf unit sales have multiple drivers in place . . . We are planning accelerating growth in Apligraf production to meet the increasing demand anticipated.*" [Emphasis added.]

129. **\$10 Million Equity Sale to Novartis.** On August 7, 2001, Organogenesis issued a release announcing that it had elected to sell \$10 million in equity to Novartis, pursuant to the terms of its amended, \$20 million stock sales agreement.

130. **2Q:01 Results.** On August 13, 2001, defendants published a release on *Business Wire*, which purported to announce financial results for the second quarter 2001, the period ended June 30, 2001, which stated that there was "sustained market demand for Apligraf and the

Company *accelerated its plans to ramp up production to meet the strong sales forecast for the second half of this year*," in addition to stating the following:

Reflecting the growth in product sales and the 2001 amendment to the agreement with Novartis, for the three months ended June 30, 2001, product sales to related party were \$1.7 million in 2001 compared with \$0.7 million for the same period in 2000. Total operating revenues were \$2.1 million in the second quarter of 2001 compared with \$1.3 million for the same quarter in 2000, excluding a \$5 million milestone payment from Novartis for the approval of Apligraf for diabetic foot ulcers. Total operating costs and expenses were \$ 9.1million during the second quarter of 2001 compared with \$8.0 million for the same quarter in 2000, excluding a \$1.2 million (\$0.04 per share) one-time severance expense in 2001 for a former executive officer. Cost of product sales increased by \$1.3 million due to increased sales of Apligraf and ramping up production to meet anticipated increased demand; research and development as well as general and administrative costs slightly decreased. Net loss was \$8.6 million (\$0.25 per share) for the second quarter of 2001 compared with a net loss of \$1.8 million (\$0.05 per share) for the same quarter in 2000.

* * *

[Defendant] Arcari said, "*Our year-to-date revenue from product sales is nearly triple that of the same period last year. Our cost of goods per unit compares favorably with the same period last year*, but is up moderately from the previous quarter due to accelerating our plans to ramp up production. To strengthen our cash position, we have exercised our right to sell Novartis \$10 million in equity. *We retain the right to sell Novartis an additional \$10 million in equity.*" [Emphasis added.]

131. **2Q:01 Form 10-Q.** The following day, August 14, 2001, the Company also filed with the SEC the Company's financial results for the second quarter of 2001, the period ended June 30, 2001, pursuant to a Form 10-Q signed by defendants Sabolinski and Arcari. The Company's Form 10-Q for the second quarter of 2001 contained the same materially false and misleading financial information as had previously been announced, in addition to reporting, in part, the following:

Basis of Presentation

The accompanying unaudited consolidated financial statements of Organogenesis Inc. have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X.... *In the opinion of management, the accompanying consolidated financial statements include all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of the financial position, results of operations and changes in cash flows for the periods presented....*

* * *

COSTS AND EXPENSES

Cost of product sales: Cost of product sales for the quarter ended June 30, 2001 increased 82% to \$2,837,000, from \$1,557,000 for the comparable quarter last year. Cost of product sales for the six-month period ended June 30, 2001 increased 66% to 5,033,000, from \$3,024,000 for the comparable period last year. These increases were due to increased unit sales of Apligraf to Novartis, additional scrap costs and higher allocations of depreciation and occupancy costs. Cost of product sales includes the direct costs to manufacture, quality inspect and package Apligraf and an allocation of our production-related indirect costs. Cost of product sales continues to exceed product sales due to the high costs associated with low volume production. *We expect production volume to increase and our margins to continue to improve during 2001. We expect that we will have to revise standard costs and the allocation of costs to product sales in the future as we continue to modify our manufacturing processes.* [Emphasis added.]

132. In addition to the foregoing, the Form 10-Q for the second quarter of 2001 also reported that the Company paid severance to a retiring senior executive, as follows:

Severance Agreement:

In May 2001, we entered into a separation of employment agreement with a former executive officer, which resulted in the recording of a one-time severance expense of \$1,233,000 during the quarter ended June 30, 2001. The separation of employment agreement provides for amounts to be paid over two years and supercedes the previous employment agreement. It has been filed as exhibit 10(ff) to this Form 10Q.